UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

MARIA WILLIAMS, Plaintiff, v. JOHNSON & JOHNSON and ETHICON, INC., Defendants.	Case Action No. 1:20-cv-00544-MSM-LDA

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

Rather than filing a complaint that is tailored to her case, Plaintiff has borrowed from a generic complaint filed in other cases and inserted a few barebones allegations specific to her circumstances. Plaintiff cannot state a claim for which relief may be granted because she has not pled sufficient facts that could plausibly show that she may prevail against Defendants under the standard set forth in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

BACKGROUND[1]

In this products liability case, Plaintiff Maria Williams alleges that she has sustained injuries from the implantation of TVT, a prescription medical device manufactured by Defendant Ethicon, Inc. for the surgical treatment of stress urinary incontinence ("SUI"). Doc. 1, Compl., ¶¶2-3. A resident of Rhode Island, Plaintiff alleges that she was implanted with the TVT on March 7, 2011, in Providence. *Id.*, ¶¶1-2. At some unspecified time thereafter, Plaintiff claims that she sustained "mesh implant complications necessitating removal, worsening mixed

[1] For purposes of Defendants' motion only, the well-pled factual allegations in the Complaint are considered to be true. *In re Fin. Oversight & Mgmt. Bd. for Puerto Rico*, 919 F.3d 638, 644 (1st Cir. 2019).

incontinence, pelvic pain, dyspareunia, difficulty voiding, dysuria, frequency, nocturia, urinary tract infections, and urgency. *Id.*, ¶3.

Plaintiff filed her Complaint on December 30, 2020. Doc. 1. Her Complaint is virtually identical to dozens of other Complaints that were filed by other Plaintiffs across the country around the same time.[2] Although Plaintiff alleges that she was implanted with a TVT, her Complaint only references that product on one occasion—Compl., ¶2—and instead generically discusses at length "Defendants' pelvic mesh products," including products that were not even designed to treat her medical condition, SUI. *See, e.g.*, Compl., ¶¶12-56.

Plaintiff's Complaint purports to assert the following causes of action: negligence, strict liability design defect, strict liability manufacturing defect, strict liability failure to warn, "Strict Liability – Defective Product," breach of express and implied warranty, fraudulent concealment, constructive fraud, "Discovery Rule, Tolling and Fraudulent Concealment," negligent misrepresentation, negligent infliction of emotional distress, violation of the Rhode Island Consumer Protection Act, gross negligence, unjust enrichment, and punitive damages. Doc. 1, ¶¶58-188. Each of these claims should be dismissed.

LEGAL ARGUMENT

"The sole inquiry under Rule 12(b)(6) is whether, construing the well-pleaded facts of the complaint in the light most favorable to the plaintiff[ ], the complaint states a claim for which relief can be granted." *Cortes-Ramos v. Martin-Morales*, 956 F.3d 36, 41 (1st Cir. 2020) (quoting *Ocasio-Hernández v. Fortuño-Burset*, 640 F.3d 1, 7 (1st Cir. 2011)). Rule 12(b)(6) authorizes a court to dismiss a cause of action that fails "to state a claim upon which relief can be

[2] *See, e.g., Langston & Ray Langston v. Johnson & Johnson*, No. 3:20-cv-03712, Doc. 1 (N.D. Tex. Dec. 23, 2020); *Merino v. Johnson & Johnson*, No. 1:20-cv-25308 (S.D. Fla. Dec. 30, 2020); *Wells v. Johnson & Johnson*, No. 5:20-cv-01301 (W.D. Okla. Dec. 29, 2020); *Harju v. Johnson & Johnson*, No. 3:20-cv-06258 (W.D. Wash. Dec. 31, 2020); *Williams v. Johnson & Johnson*, No. 1:20-cv-00544 (D.R.I. Dec. 30, 2020).

granted." To avoid dismissal under Rule 12(b)(6), the complaint must contain "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citation omitted). "A claim has facial plausibility when the plaintiff pleads *factual content* that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (emphasis added). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* A conclusory assertion is a conclusion without "factual enhancement" to support the conclusion. *Id.* In other words, the complaint must offer more than an "unadorned, the-defendant-unlawfully-harmed-me accusation" to defeat dismissal. *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citations omitted)).

Although the court must accept well-pleaded facts as true, conclusory allegations are not entitled to a presumption of truth. *Id.* at 678-79. Additionally, when a complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility." *Id.* (citation and quotations omitted).

I. Plaintiff has not sufficiently pled a design defect claim.

In Count II of her Complaint, Plaintiff alleges a strict liability design defect cause of action, and she asserts other causes of action (ie. negligence, gross negligence, and negligent infliction of emotional support) that are predicated in part on a design defect theory. To prove her design defect claim, Plaintiff must show "(1) that there was a defect in the design . . . of the product in question; (2) that the defect existed at the time the product left the hands of . . . defendant; (3) that the defect rendered the product unreasonably dangerous, and by unreasonably dangerous it is meant that there was a strong likelihood of injury to a user who was unaware of the danger in utilizing the product in a normal manner; (4) that the product was being used in a

way in which it was intended at the time of the accident; and (5) that the defect was the proximate cause of the accident and plaintiff's injuries." *Raimbeault v. Takeuchi Mfg. (U.S.), Ltd.*, 772 A.2d 1056, 1063 (R.I. 2001) (quoting *Crawford v. Cooper/T. Smith Stevedoring Co.*, 14 F. Supp. 2d 202, 211 (D.R.I. 1998)).[3]

Rather than pleading sufficient facts from which it could plausibly be shown that there was a design defect with TVT and that this "defect" caused Plaintiff's injuries, the Complaint contains only vague and conclusory allegations. For instance, the Complaint contains no allegations about the specific design of TVT, instead generically addressing the alleged design of numerous pelvic mesh products. Doc. 1, ¶67. Further, other than criticizing the products for containing polypropylene, the Complaint states very little about how the design of the products was flawed, and instead, it focuses on conclusory assertions that the products had a propensity for complications without explaining how the design of the products gave them any such propensity. *Id.*[4]

Even were the Court to find that Plaintiff sufficiently identifies a design defect, she pleads no facts whatsoever that would plausibly link her injuries to the alleged defect(s). Instead, she merely states as follows: "As a direct and proximate result of the product's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo future medical treatment and procedures, have suffered financial or

[3] There should be no dispute that the law of Rhode Island applies to Plaintiff's substantive claims because Plaintiff alleges to be a Rhode Island resident and that she was implanted with the TVT in Rhode Island. Compl., ¶¶1-2; *Harodite Indus., Inc. v. Warren Elec. Corp*, 24 A.3d 514, 526 (R.I. 2011) (applying most significant relationship test).

[4] For instance, Plaintiff alleges "biomechanical issues with the design of the products, including, but not limited to, the propensity of the products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract resulting in injury." *Id.*, ¶67.c. The Complaint, however, does not identify how the design of the products lead to these alleged biomechanical issues.

economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages." Doc. 1, ¶68. Indeed, Plaintiff pleads no facts that would show that her injuries are plausibly the result of a defect with the TVT as opposed to an injury that is consistent with any SUI surgery.

In numerous cases involving synthetic mesh products, courts have dismissed other design defect claims where the plaintiff similarly did not plead sufficient facts that would plausibly show a design defect or causation.[5] For instance, very recently, a Minnesota federal district court found that the plaintiff's causation allegations were "legal conclusions devoid of any factual enhancement" that "do no more than state, in a conclusory manner, that the [mesh product's] design defect caused [the plaintiff's] injuries." *Dolan v. Bos. Sci. Corp.*, 2021 WL 698777, at *2 (D. Minn. Feb. 23, 2021). The court further stated:

> What the Complaint lacks is factual allegations specific to Dolan and her alleged injuries. Among other pleading defects, it is not clear from the Complaint which of the numerous enumerated design defects Dolan claims caused her injury, whether she was pain-free before the implantation of the Solyx sling, what

[5] *See, e.g., Moore v. C.R. Bard, Inc.*, 217 F. Supp. 3d 990, 995-96 (E.D. Tenn. 2016) (finding that complaint did not sufficiently allege a design defect or causation); *Meredith v. Medtronic, Inc.*, 2019 WL 6330677, at *4 (S.D. Iowa Oct. 25, 2019) (dismissing design defect allegations on Rule 12 and noting that the plaintiff did "not allege, however, how the tissue attachment properties of the [mesh product's] polyester caused his injuries" and did not "distinguish the injuries caused by the Parietex Mesh's alleged design defect from complications from the hernia repair surgeries."); *Pellegrin v. C.R. Bard*, 2018 WL 3046570, at *5 (E.D. La. June 20, 2018) (finding that "Plaintiff fails to sufficiently allege what aspect of defendants' product design caused it to abrade tissues [or] how the alleged defect contributed to her specific injuries"); *Nowell v. Medtronic Inc.*, 273 F. Supp. 3d 1166, 1249-50 (D.N.M. 2019), *appeal pending* (dismissing design defect claims where plaintiff "has not alleged a plausible defect in the Defendants' [hernia] mesh," and instead, set forth vague and conclusory allegations); *Baca v. Johnson & Johnson*, 2020 WL 6450294, at *4 (D. Ariz. Nov. 2, 2020) (dismissing pelvic mesh design defect claim where the complaint "simply fail[s] to show how the Product caused *this* Plaintiff's specific injury"); *Hernandez v. Johnson & Johnson*, 2021 WL 320612, at *3 (E.D. Wash. Jan. 8, 2021) ("[A]lthough she alleges that '[a]s a result of having the Product implanted in her, Plaintiff has experienced significant' damages, [plaintiff] does not plausibly allege the device's *design itself* caused the damages") (emphasis in original); *McCormick v. Caldera Med., Inc.*, 2021 WL 488340, at *4 (S.D. Ohio Feb. 2, 2021) ("Plaintiff's amended complaint contains no specific details regarding how the particular product implanted in her was supposedly deficient and presents no allegation as to how that defect caused her harm.").

> outcome Dolan anticipated, or what other factors may have contributed to Dolan's injuries.

Id. For these same reasons, the Court should dismiss Plaintiff's design defect claims here.

II. Plaintiff has not sufficiently pled a manufacturing defect claim.

For similar reasons, the Court should dismiss Plaintiff's manufacturing defect claims. In Count III of her Complaint, Plaintiff alleges a strict liability manufacturing defect cause of action based on the notion that "[t]he products implanted in the Plaintiff were not reasonably safe for their intended use and were defective as described herein as a matter of law with respect to their manufacture, in that they deviated materially from Defendants' design and manufacturing specifications." Doc. 1, ¶71.[6] To proceed under a manufacturing defect theory, "a plaintiff must show a product defect caused by a mistake or accident in the manufacturing process." *Swajian v. Gen. Motors Corp.*, 916 F.2d 31, 35 (1st Cir. 1990) (applying Rhode Island law); *see also Guilbeault v. R.J. Reynolds Tobacco Co.*, 84 F. Supp. 2d 263, 280-81 (D. R.I. 2000) (noting that a plaintiff must show a "deviation from defendant's manufacturing process").

Plaintiff, however, does not allege *how* her TVT deviated from Ethicon, Inc.'s design and manufacturing specifications such that it was different than other TVTs that were manufactured and such that it was different than intended. Nor does Plaintiff allege facts that would show her claimed injuries are attributable to any such manufacturing defect. Instead, she again makes the conclusory assertion that "[a]s a direct and proximate result of the products' aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and corrective surgery and hospitalization, have suffered financial or economic loss, including, but

[6] Other counts in the Complaint (ie. negligence, gross negligence, and negligent infliction of emotional support) appear to also be predicated in part on a manufacturing defect theory.

not limited to, obligations for medical services and expenses, and/or lost income, and other damages." Doc. 1, ¶73.

In numerous recent cases, other federal district courts have dismissed manufacturing defect claims against mesh device manufacturers that were similarly conclusory and not supported by any substantive factual allegations.[7] For these same reasons, the Court should dismiss Plaintiff's manufacturing defect claims.

III. Plaintiff has not sufficiently pled a failure to warn claim.

In Count IV of her Complaint, Plaintiff alleges a strict liability failure to warn claim and many of her other claims are based, at least in part, on the notion that Defendants failed to adequately warn of dangers associated with TVT. "Rhode Island recognizes a tort cause of action against a seller of goods if the seller fails 'to warn purchasers of a dangerous defect in the

[7] *See, e.g.*, *Meredith*, 2019 WL 6330677, at *5 (dismissing manufacturing defect claim at Rule 12 stage and noting that plaintiff "does not allege a specific manufacturing defect, nor does he proffer circumstantial evidence demonstrating a manufacturing defect"); *Shapiro v. NuVasive, Inc.*, 2019 WL 5742159, at *3 (S.D. Fla. Nov. 5, 2019) (dismissing manufacturing defect claim because complaint "did not sufficiently identify a defect in the product or demonstrate how the device 'deviated from manufacturing specifications'") (citation omitted); *Cofresi v. Medtronic, Inc.*, 450 F. Supp. 3d 759, 767 (W.D. Tex. 2020) (dismissing manufacturing defect claim because "nowhere in the [Complaint] does Plaintiff allege that a particular mishap occurred in the manufacturing process that rendered the Prolene Mesh unreasonably dangerous"); *Bustamante v. Atrium Med. Corp.*, 2020 WL 583745, at *6 (S.D.N.Y. Feb. 6, 2020) ("Plaintiffs have failed to identify what specific component(s) of the device were defective and have failed to adequately allege any deviations from the manufacturing process, improper workmanship, or defective materials."); *Taylor v. Medtronic, Inc.*, 2020 WL 886118, at *7 (N.D.N.Y. Feb. 24, 2020) ("These generic and conclusory statements do not show how Plaintiff's specific [hernia] mesh implant was flawed or deviated in quality and performance form other mesh implants produced during the manufacturing process"); *Baca*, 2020 WL 6450294, at *3 ("[T]he Complaint does not identify a specific manufacturing defect, either by failing to manufacture the Product as designed, or by failing to manufacture the particular Product in a similar way as other identical units."); *Kuchenbecker v. Johnson & Johnson*, 2019 WL 4416097, at *2 (S.D. Fla. Sept. 16, 2019) (finding that, because "the Complaint fails to specify how the device implanted in the Plaintiff deviated from manufacturing specifications," "the Court simply cannot draw the reasonable inference that Defendants defectively manufactured the" pelvic mesh device); *Green v. W.L. Gore & Assocs., Inc.*, 2020 WL 1666790, at *8 (D. Idaho Apr. 3, 2020) (dismissing manufacturing defect claims because the plaintiff "does not allege how the supposed defect caused any of the pain or other damages *she* suffered"); *Hernandez*, 2021 WL 320612, at *4 (dismissing manufacturing defect claims because the plaintiff "fails to identify any deviation from the design or other manufacturing flaw in the TVT-O that doctors implanted in her . . . and fails to adequately allege causation").

product if the seller knows or has reason to know that the product poses a danger to consumers.'" *DiPalma v. Westinghouse Elec. Corp.*, 938 F.2d 1463, 1466 (1st Cir. 1991) (quoting *Scittarelli v. Providence Gas Co.*, 415 A.2d 1040, 1043 (R.I. 1980)).

The widely-accepted learned intermediary doctrine recognizes "(1) that manufacturers of prescription drugs and medical devices discharge their duty to of care to patients by providing adequate warnings to prescribing physicians, and (2) that any failure to warn cannot be considered a proximate cause of a subsequent injury if the physician was fully aware of the dangers that would have been included in an alternative warning." *In re Zyprexa Prods. Liab. Litig.*, 277 F.R.D. 243, 249 (E.D.N.Y. 2011) *aff'd sub nom. Greaves v. Eli Lilly & Co.*, 503 F. App'x 70, 71 (2d Cir. 2012) (citation omitted). Although this doctrine "has been neither adopted nor rejected in Rhode Island," it "has been adopted by 'almost every state,'" and at least one court has found that "[i]t is highly likely that the Rhode Island Supreme Court will accept" this doctrine. *Id.* at 250 (citations omitted). The learned intermediary doctrine recognizes that, because the physician communicates directly with the patient, the manufacturer must warn only the physician of the dangers associated with the product, and then rely on the physician's expertise to convey the relevant warning information to the patient.

The Complaint does not adequately plead how TVT's warnings were inadequate because it does not address what was contained in that product's warnings and only generally discusses all pelvic mesh products allegedly manufactured by Defendants. Further, the Complaint does not plead sufficient facts that would plausibly show how Plaintiff's injuries were proximately caused by any alleged deficiencies in the warnings. The Complaint makes no mention of the surgeon who implanted the TVT. It does not allege facts that would show how the unidentified implanting surgeon acted in reliance on deficiencies in Ethicon's warnings or how (if at all)

he/she would have acted any differently if different warnings had been provided. Instead, Plaintiff only asserts in conclusory fashion that "[a]s a direct and proximate result of the products' aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, have sustained permanent injury, have undergone medical treatment and will likely undergo further medical treatment and procedures, have suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages." Compl., ¶80.

As determined by many other courts, such threadbare allegations are not enough to survive a Rule 12(b)(6) motion.[8]

[8] *See, e.g., Nowell*, 372 F. Supp. 3d at 1254 (dismissing failure to warn claims and finding that plaintiff "must direct the Court to specific statements" and noting that plaintiff's "concerns are too generalized to assist the Court in evaluating the sufficiency of the Defendants' warnings"); *Bustamante*, 2020 WL 583745, at *7 (dismissing failure to warn claims and stating that "[n]otably absent from Plaintiffs' Amended Complaint is the exact language of the warnings contained on the device"); *Moore*, 217 F. Supp. 3d at 995 ("While the amended complaint alleges that the defendants failed to adequately warn plaintiff of various risks and characteristics of the mesh products, plaintiff has not sufficiently alleged facts to permit the Court to infer that either defendant's allegedly deficient warnings caused plaintiff's injuries.") (citation to record omitted); *Taylor*, 2020 WL 886118, at *6 (dismissing failure to warn claims where complaint "did not identify what warnings were given" and provided conclusory assertions); *Marrufo v. Ethicon, Inc.*, 2020 WL 7680562, at *3 (W.D. Tex. Nov. 20, 2020) ("A plaintiff's pleadings are insufficient when they do not identify the warning that her doctor received, alleged how it was inadequate, demonstrate that a different warning would have changed the doctor's action, or otherwise include facts necessary to allege the failure to warn caused her injury"); *Cosh v. Atrium Med. Corp.*, 2020 WL 583826, at *4 (S.D.N.Y. Feb. 6, 2020) (finding that "Plaintiffs' allegations of inadequate warnings are, for the most part, conclusory," that "[n]otably absent from Plaintiffs' Amended Complaint is the exact language of the warnings contained on the device," and therefore, "they do not provide a reliable basis to support an inference that [Defendant] misrepresented anything") (citation omitted); *Rhodes v. Covidien LP*, 2019 WL 2162845, at *4 (E.D. La. May 17, 2019) (dismissing failure to warn claims and noting that plaintiff "does not allege how defendants' alleged failure to warn specifically caused his injuries—*i.e.*, facts showing that a 'proper warning would have changed the decision of the treating physician'") (citation omitted); *Baca*, 2020 WL 6450294, at *3 (finding that the "Complaint fails to allege facts raising a plausible failure to warn claim" where it did not provide sufficient factual allegations concerning "what Defendants told the health-care provider and whether inadequacies in those warnings caused Plaintiff's injuries"); *Pellegrin*, 2018 WL 3046570, at *4 ("[P]laintiff fails to assert that the alleged inadequate warning is causally connected to her injuries, which renders her inadequate warning claim implausible"); *Hernandez*, 2021 WL 320612, at *4 (dismissing failure to warn claims because the plaintiff "does not sufficiently allege that any failure to warn proximately caused her injuries"); *Cofresi*, 450 F. Supp. 3d at 767 (dismissing failure to warn claims due to lack of specificity); *Meredith*, 2019 WL 6330677, at *6 (same).

IV. "Strict Liability – Defective Product" is not a recognized cause of action.

Copying similar complaints filed in other states, Plaintiff purports to plead a cause of action of "Strict Liability – Defective Product." Doc. 1, Count V. Rhode Island only recognizes a strict product liability claim under three theories: design defect, manufacturing defect, and failure to warn. *Guilbeault*, 84 F. Supp. 2d at 268; *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 779 (R.I. 1988). "Strict Liability – Defective Product" is not a recognized cause of action, and Count V of the Complaint is duplicative of Counts II-IV. Therefore, it should be dismissed.

V. The Court should dismiss Plaintiff's Negligence (Count I), Negligent Infliction of Emotional Distress (Count XII) and Gross Negligence (Count XIV).

Plaintiff's negligence, gross negligence, and negligent infliction of emotional distress claims are all predicated on the same three theories upon which her strict liability claims are based—design defect, manufacturing defect, and failure to warn. *See* Compl., Counts I, XII & XIV; *see also Guilbeault*, 84 F. Supp. 3d at 268 ("A product may be unreasonably dangerous due to one or more of three defects: design, marketing (failure to warn) or manufacturing."). The elements to prove these claims under a negligence theory are essentially the same as a strict liability theory, although Plaintiff bears a heightened burden, including showing that Defendants knew or should have known of a defect. *See DiPalma*, 938 F.2d at 1466 ("It is clear under Rhode Island law that the duty to warn, the violation of which is actionable by means of the so-called strict liability cause of action, is measured, in all respects material to this case, by the same standard as the duty to warn that is enforceable in a negligence cause of action."); *Gray v. Derderian*, 472 F. Supp. 2d 172, 182 (D.R.I. 2007) ("The requirements of a strict products liability claim overlap significantly those of a negligence claim, with the difference residing in a negligence claim's additional requirement that the defendant knew or had reason to know of the

product's defect."); *Guilbeault*, 84 F. Supp. 2d at 268, 280 (same and also noting that "it is unclear to this Court why plaintiff would include a negligent manufacturing claim in this Complaint since strict liability will lie due to a manufacturing defect without, as noted above, the additional requirement that defendant knew or should have known of the defect"); *Raimbeault v. Takeuchi Mfg. (U.S.), Ltd.*, 772 A.2d 1056, 1063 (R.I. 2001) (finding failure of both negligence and strict liability claims); *Thomas v. Amway Corp.*, 488 A.2d 716, 722 (R.I. 1985) (same).

Thus, for the same reasons that Plaintiff's strict liability claims fails to satisfy the *Twombly/Iqbal* pleading standard, her negligence-based claims also fail to satisfy that standard, and therefore, should be dismissed.

Plaintiff's negligent infliction of emotional distress and gross negligence claims are also subject to dismissal because Plaintiff has not pled sufficient facts that could plausibly establish other essential elements of that cause of action. "A claim of negligent infliction of emotional distress has four elements: (1) the conduct must be intentional or in reckless disregard of the probability of causing emotional distress, (2) the conduct must be extreme and outrageous, (3) there must be a causal connection between the wrongful conduct and the emotional distress, and (4) the emotional distress in question must be severe." *Swerdlick v. Koch*, 721 A.2d 849, 862 (R.I. 1998) (quoting *Champlin v. Washington Trust Co. of Westerly*, 478 A.2d 985, 988–89 (R.I. 1984)). Plaintiff does not plead any facts that would show that she has sustained any severe emotional distress. For instance, in Paragraph 3 of her Complaint, Plaintiff alleges that she "developed complications arising from the implant of the Ethicon pelvic mesh product, including mesh implant complications necessitating removal, worsening mixed incontinence, pelvic pain, dyspareunia, difficulty voiding, dysuria, frequency, nocturia, urinary tract infections, and urgency"—mentioning nothing about any emotional distress, much less severe emotional

distress. Doc. 1. There is no allegation in the Complaint that Plaintiff has sought professional help for any alleged emotional injuries. *See Doe v. Brown Univ.*, 209 F. Supp. 3d 460, 478 (D.R.I. 2016), *aff'd,* 943 F.3d 61 (1st Cir. 2019) (finding that conclusory allegations of emotional distress are insufficient); *Lisnoff v. Stein*, 925 F. Supp. 2d 233, 241-42 (D.R.I. 2013).

In addition, a plaintiff may satisfy the "extreme and outrageous" element, "only where the conduct has been so outrageous in character, and so extreme in degree, as to go beyond all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized community." *Swerdlick*, 721 A.2d at 862-63 (quoting Restatement (Second) Torts, § 46 cmt. d). Similarly, "[g]ross negligence, under Rhode Island law, 'demands evidence of near recklessness or shockingly unjustified and unreasonable action.'" *Petro v. Town of W. Warwick ex rel. Moore*, 889 F. Supp. 2d 292, 335-36 (D.R.I. 2012) (citation omitted); *see also id.* (finding that "[t]here is a clear and significant difference between" gross negligence and negligence and that "one requires only a showing of unreasonableness while the other demands evidence of *near recklessness or shockingly unjustified and unreasonable action*") (emphasis in original).

"It [is] for the Court in the first instance to determine whether the defendant[s'] alleged conduct, set out in the complaint, could reasonably be regarded as so extreme and outrageous to result in liability." *Brown Univ.*, 209 F. Supp. 3d at 478 (quoting *Clift v. Narragansett Television L.P.*, 688 A.2d 805, 813 (R.I. 1996)). Plaintiff's Complaint does not allege any conduct that could be construed as extreme or outrageous. Instead, it merely faults Ethicon for marketing a medical device that was cleared by the FDA and continues to be approved by the FDA to this date. *See id.* (finding that the plaintiff did not plead sufficient facts to "rise to this high standard"); *Cofresi v. Medtronic, Inc.*, 450 F. Supp. 3d 759, 768 (W.D. Tex. 2020) (dismissing plaintiff's claims for punitive damages and gross negligence in accordance with Rule

12 in polypropylene mesh case where the plaintiff failed to plead sufficient facts "to show that Defendant Ethicon acted with an extreme degree of risk or was consciously indifferent to the safety of others by creating the Prolene Mesh in question"). Thus, Plaintiff's negligent infliction of emotional distress and emotional distress claims are subject to dismissal for this reason as well.

VI. Plaintiff may not bring claims for breach of warranty.

The Court should dismiss Plaintiff's breach of express and implied warranty claims set forth in Counts VI-VII of her Complaint because her Complaint does not plead facts that would plausibly show that she is entitled to relief under the *Twombly/Iqbal* standard for the reasons set forth below.

A. Breach of Express Warranty

In Count VI of her Complaint, Plaintiff alleges that Defendants made unspecified "express warranties and guarantees that the products were safe, merchantable, and reasonably fit for their intended purposes," that she relied on these alleged warranties, and that "Defendants breached these express warranties because the product implanted in the Plaintiff were [sic] unreasonably dangerous and defective, as described herein, and not as Defendants have represented." Doc. 1, ¶¶92-93.

Under R.I. Gen. Laws Ann. § 6A-2-313(1), "[e]xpress warranties by the seller are created as follows: (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise[;] (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description[; and] (c) Any sample or model which is made part of the basis of the bargain creates

an express warranty that the whole of the goods shall conform to the sample or model." Further, a "plaintiff who claims breach of express warranty has the burden of proving that the statements or representations made by the seller induced her to purchase that product and that she relied upon such statements or representations." *Thomas v. Amway Corp.*, 488 A.2d 716, 720 (R.I. 1985).

Plaintiff does not plead any specific affirmation of fact or promise made by Ethicon related to TVT that was breached. Her conclusory assertions do not suffice. *See, e.g., Taylor*, 2020 WL 886118, at *8 (dismissing breach of express warranty claim and noting that the plaintiff "fails to identify any express statements Defendants made, when such statements were made, or to whom they were made"); *Bustamante*, 2020 WL 583745, at *9 (dismissing breach of warranty claim because "Plaintiffs fail to identify a specific warranty made by Defendants that was relied upon by Plaintiffs"); *Pellegrin*, 2018 WL 3046570, at *6 (finding that "Plaintiff's claim for breach of warranty is nothing more than a 'threadbare recital[ ] of the elements of [the] cause of action, supported by mere conclusory statements,' that "plaintiff's vague and conclusory allegations fail to specify the contents of defendants' representations or how they were factually untrue or inadequate," and that the plaintiff "must specify the warranty in question and explain why the warranty is untrue") (quoting *Iqbal*, 556 U.S. at 678); *Hernandez*, 2021 WL 320612, at *5 ("While Plaintiff asserts that the TVT-O 'did not conform to an express warranty made by Defendants,' she does not state the contents of the alleged express warranty or how Defendants allegedly breached the warranty.").

Moreover, Plaintiff does not plead facts that would show that she relied on any purported warranty made by Defendants. *See Thomas*, 488 A.2d at 720. It is evident from the Complaint that Plaintiff was not in privity of contract with either of the Defendants, and she identifies no

representations from Defendants that were conveyed to her. Therefore, she may not bring a breach of express warranty claim. *See, e.g., Coleman v. DePuy Synthes Sales, Inc.*, 2018 WL 1811556, at *4 (M.D. Tenn. Apr. 17, 2018) (dismissing breach of express warranty claim where there was no evidence that the plaintiff purchased the medical device from the defendant or relied on any affirmation of fact to her).

B. Breach of Implied Warranty

"In order to establish liability for breach of the implied warranty of merchantability, a plaintiff must 'prove that the product is defective, that it was in a defective condition at the time it left the hands of the seller, and that said defect was the proximate cause of the injury.'" *Marketing Design Source, Inc. v. Pranda North Am., Inc.* 799 A.2d 267, 272 (R.I. 2002) (quoting *Lariviere v. Dayton Safety Ladder Co.*, 525 A.2d 892, 896 (R.I. 1987)). Thus, the proof required to prove an implied warrant claim is duplicative of the proof required to prove Plaintiff's strict liability claims set forth in Counts II-IV of her Complaint. *See Castrignano*, 546 A.2d at 783 (finding that "strict liability and implied warranty of merchantability are parallel theories of recovery" and "[o]n the facts presented in this case the two theories are indistinguishable"); *Scittarelli v. Providence Gas Co.*, 415 A.2d 1040, 1046-47 (R.I. 1980). Accordingly, Plaintiff cannot state a breach of implied warranty claim for the same reasons that she cannot state a claim based on a design defect, manufacturing defect, or failure to warn theory. *See* Sections I-III above.

VII. Plaintiff has not properly pled claims based on fraud and negligent misrepresentation.

Plaintiff's claims of fraudulent concealment (Count VIII), constructive fraud (Count IX), and negligent misrepresentation (Count XI) fail for the same reasons that her strict liability claims fail. Each of these claims is premised on the notion that Defendants failed to warn of a

product defect, and thus, the Court should dismiss these claims for the same reasons that it dismisses Plaintiff's failure to warn claims.

These claims also fail because Plaintiff has not pled them under the heightened standard of particularity required by Fed. R. Civ. P. 9(b). *See Koch v. I-Flow Corp.*, 715 F. Supp. 2d 297, 304 (D.R.I. 2010) (finding that Rule 9(b) applies to fraud claims as well as negligent misrepresentation claims premised on the notion that the defendant acted knowingly).[9] To satisfy Rule 9(b), "[t]he Complaint must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Sheet Metal Workers Local No. 20 Welfare & Benefit Fund v. CVS Health Corp.*, 221 F. Supp. 3d 227, 230 (D.R.I. 2016) (internal quotation marks omitted). "In other words, Rule 9(b) requires plaintiffs to allege the 'who, what, when, where, and how' of the alleged fraud." *Id.* (quoting *United States ex rel. Ge v. Takeda Pharm. Co. Ltd.*, 737 F.3d 116, 123 (1st Cir. 2013)).

Plaintiff's Complaint, however, falls far short of specifying the time, place and content of Defendants' alleged misrepresentations. Instead, the Complaint contains vague assertions that Defendants supposedly failed to disclose material information. Such flimsy accusations do not suffice.

The district court's findings in *Koch*, *supra*, are instructive. There, the plaintiff also alleged similarly vague accusations under different species of fraud in another products liability case against a medical device manufacturer. *Koch*, 715 F. Supp. 2d at 302-305. Finding that the plaintiff did not comply with Rule 9(b), the court in found as follows:

> Examination of Plaintiff's Complaint yields scant evidence of specific factual allegations. In Count V, Plaintiff asserts:

[9] In paragraph 125, Plaintiff alleges as part of her negligent misrepresentation claim that Defendants acted knowingly, and therefore, Rule 9(b) applies to this claim.

> The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff SHEREEN KOCH and/or the FDA, and/or the public in general, that said products, the pain pumps and/or bupivacaine products, had been tested and were found to be safe and/or effective for the control of pain after shoulder surgery.
>
> That representations made by Defendants were, in fact, false.
>
> When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

(Complaint, ¶¶ 114–116.) Although the allegations continue, there is little more beyond the bare claim that Defendants committed the tort of fraudulent misrepresentation. In Count VI for fraudulent concealment, Plaintiff states, "[a]t all times during the course of dealing between Defendants and Plaintiff SHEREEN KOCH and/or Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of the pain-pumps and/or bupivacaine products for their intended use." *Id.* ¶ 127. Plaintiff then continues with a lengthy list of the dangers of the treatment, which she says Defendants "fraudulently concealed and intentionally omitted." *Id.* ¶ 130.

In Count VIII for fraud and deceit, Plaintiff alleges that Defendants intentionally disseminated false information, and failed to disseminate other correct information, to "the public, the Plaintiff SHEREEN KOCH, her doctors, hospitals, healthcare professionals, and/or the FDA." *Id.* ¶ 149. As for the "what, where and when" portion of the Rule 9(b) inquiry, Plaintiff states:

> The information distributed to the public, the FDA, and the Plaintiff SHEREEN KOCH by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.
> *Id.* ¶ 152.

Because these allegations fail to set forth specific and particular facts concerning Defendants' alleged misrepresentations, they are insufficient to satisfy the requirements of Rule 9(b), as elucidated by the First Circuit.

Id. at 303-04.

In dismissing similar fraud claims in another pelvic mesh products liability case, a Kentucky federal district court recently found as follows:

> First, the complaint fails to identify who made the allegedly fraudulent statements and concealed material information, "beyond the logical inference" that it was the defendants. *House v. Bristol-Myers Squibb Co.*, No. 3:15-CV-894-JHM, 2017 WL 55876, at *8, 2016 U.S. Dist. LEXIS 180869, at *23-*24 (W.D. Ky. Dec. 29, 2016). Moreover, the plaintiffs failed to specify each defendant's role with respect to the fraud. *See Anderson v. Pine S. Capital*, 177 F. Supp. 2d 591, 596-97 (W.D. Ky. 2001) ("[E]ach defendant's role must be particularized with respect to their alleged involvement in the fraud."). Second, the plaintiffs do not state which specific statements are allegedly fraudulent. The complaint only mentions vague representations that the pelvic mesh products "were not as safe as other products and procedures" and were "more effective than other products and procedures," and alleges that the defendants "concealed and suppressed material information, including limited clinical testing" and "misrepresented the safety and efficacy of the Products." This is not enough under Rule 9(b). *See Bristol-Myers*, 2017 WL 55876, at *8, 2016 U.S. Dist. LEXIS 180869, at *23 (finding that vague representations that the drugs "had been tested and found to be safe and effective for the treatment of diabetes" and "were safer than alternative medications" were insufficient under Rule 9(b)). Third, the plaintiffs' complaint here fails to specify the time, nature, and place of the alleged misrepresentations, and no fraudulent communication or its source is identified. *See id.* The complaint also does not include where or when the alleged statements were made, beyond highly generalized allegations. *Id.* at *24.

Blair v. Johnson & Johnson, 2020 WL 1172715, at *6 (W.D. Ky. Mar. 11, 2020) (citation to the record omitted); *see also Bustamante*, 2020 WL 583745, at *6 (dismissing fraudulent concealment claims and finding that plaintiffs failed to adequately allege reliance and that the "Amended Complaint lacks details regarding whether and how Mr. Bustamante and his physician reviewed and relied upon Defendants' statements"). Plaintiff's Complaint is similarly deficient.

These claims also fail for other reasons. As it relates to her fraudulent concealment claim, "[l]ability for fraudulent concealment arises where '[o]ne party to a transaction who by concealment or other action intentionally prevents the other from acquiring material information is subject to the same liability to the other, for pecuniary loss as though he had stated the nonexistence of the matter that the other was thus prevented from discovering.'" *French v. Isham*, 801 F. Supp. 913, 922 (D.R.I. 1992) (citation omitted). Plaintiff does not plead facts that

would show that Defendants prevented her from obtaining material information, and because she was not a party to the transaction at issue, she could not possibly have standing to assert a fraudulent concealment claim.

Similarly, a plaintiff asserting a claim for negligent misrepresentation must show that he/she "act[ed] in justifiable reliance on the misrepresentation." *Cruz v. DaimlerChrysler Motors Corp.*, 66 A.3d 446, 453 (R.I. 2013). As someone who was not a party to the transaction, Plaintiff does not plead facts that could plausibly show that she justifiably relied on any assertion by Defendants.

Finally, constructive fraud "is the breach of some legal or equitable duty which, irrespective of moral guilt, the law declares fraudulent because of its tendency to deceive others, to violate confidence, or injure public interests." *Cardoso v. Mendes*, No. C.A. 94-6214, 1998 WL 321439, at *11 (R.I. Super. Ct. June 9, 1998) (internal quotation marks and citation omitted). Where there is no fiduciary duty owed to a party, a constructive fraud claim will fail. *Aetna Bridge Co. v. Carrillo*, No. C.A. 98-0235, 2001 WL 1006775, at *6 (R.I. Super. Ct. Aug. 2, 2001). Because Plaintiff has not pled and cannot plead that she was in a fiduciary relationship with Defendants, she cannot pursue a constructive trust claim.

VIII. The Court should dismiss Plaintiff's consumer protection claim.

In Count XIII of her Complaint, Plaintiff alleges that Defendants violated the Rhode Island Unfair Trade Practice and Consumer Protection Act, R.I. Gen. Laws §§ 6-13-1-1, *et seq.* ("the Act"), by engaging in fraudulent and deceptive conduct. The Court should dismiss this claim for several reasons.

First, this claim is predicated on the notion that Defendants failed to warn of risks associated with TVT. Thus, for the same reasons that the Court should dismiss Plaintiff's failure

to warn claims, it should dismiss her consumer protection claims. Further, because Plaintiff's consumer protection claim is rooted in fraud, she must satisfy Rule 9(b)'s heightened requirement of pleading facts supporting the claim with particularity. *Mulder v. Kohl's Dep't Stores, Inc.*, 865 F.3d 17, 21-22 (1st Cir. 2017). For the same reasons set forth in Section VII above, the Complaint does not plead with particularity sufficient facts to support a violation of the Act. Instead, it makes vague, sweeping statements without setting forth basic facts about the "who, what, when, where, and how" of the alleged conduct. *See also Hernandez,* 2021 WL 320612, at *5 (finding that "Plaintiff's Complaint alleges sparse facts to support an unfair or deceptive act or practice by Defendants" and that generalized factual assertions "are not 'accompanied by the who, what, when, where, and how of the misconduct charged'") (citation omitted).

Moreover, the Act contains an exemption when the challenged activity is otherwise subject to government regulation: "Nothing in this chapter shall apply to actions or transactions permitted under laws administered by the department of business regulation or other regulatory body or officer acting under statutory authority of this state or the United States." R.I. Gen. Laws § 6-13.1-4. Thus, "this statutory cause of action does not exist when the Defendant's challenged actions are subject to federal or state regulation." *Petrarca v. Garrison Prop. & Cas. Ins. Co.*, No. CV 18-454-WES, 2019 WL 1453058, at *2 (D.R.I. Apr. 2, 2019); *see also* State v. Piedmont Funding Corp., 382 A.2d 819, 822 (R.I. 1978) (finding that "all those activities and businesses which are subject to monitoring by state or federal regulatory bodies or officers" are "clearly exempted"). As acknowledged in the Complaint, the manufacture and marketing of TVT is subject to regulation by the FDA. Compl., ¶¶20-44. Therefore, she cannot pursue a claim under the Act.

Finally, Plaintiff does not have standing. Only a "purchaser" of a good or service may seek recovery under the Act. R.I. Gen. Laws § 6–13.1–5.2. Because the TVT was not sold to Plaintiff, she cannot pursue a claim under the Act. *See Laccinole v. Appriss, Inc.*, 453 F. Supp. 3d 499, 506 (D.R.I. 2020) (dismissing consumer protection claim where plaintiff "describes himself as a 'consumer' in a conclusory manner . . . but he does not allege that he purchased good or services from [defendant], nor was he asked to purchase goods or services from" the defendant and "does not offer well-pleaded facts to show that he himself has the necessary vendor-consumer relationship"); *Kelley v. Cowesett Hills Associates*, 768 A.2d 425, 431 (R.I. 2001) (finding that "a plaintiff must establish that he or she is a consumer" and that the plaintiff (who was a tenant) was not a consumer in a transaction in which her landlord purchased goods from the defendant).

For all of these reasons, Plaintiff's claims under the Act should be dismissed.

IX. Plaintiff cannot pursue an unjust enrichment claim.

The Court should dismiss Plaintiff's unjust enrichment claim set forth in Count XV because her claims lie in tort. Unjust enrichment is "[t]he retention of a benefit conferred by another, who offered no compensation, in circumstances where compensation is reasonably expected." *South Cnty. Post & Beam, Inc. v. McMahon*, 116 A.3d 204, 211 (R.I. 2015) (quoting *Black's Law Dictionary* 1771 (10th ed. 2014)) (internal quotation marks omitted). To recover under a claim of unjust enrichment, a plaintiff must prove "(1) that he or she conferred a benefit upon the party from whom relief is sought; (2) that the recipient appreciated the benefit; and (3) that the recipient accepted the benefit under such circumstances that it would be inequitable for [the recipient] to retain the benefit without paying the value thereof." *Id.* at 210-11 (internal

quotation marks and citations omitted). Unjust enrichment claims are based in quasi-contract. *Id.*

Plaintiff's claim here does not sound in contract or quasi-contract, but in tort. Thus, "her claim for unjust enrichment is legally irrelevant in a tort-based product liability suit." *Hosbrook v. Ethicon, Inc.*, No. 3:20-CV-88, 2020 WL 5214644, at *8 n.7 (S.D. Ohio Sept. 1, 2020). In any event, even if Plaintiff could bring an unjust enrichment claim, the premise of her claim is that Defendants were unjustly enriched because the TVT was not "safe and effective." Compl., ¶173. As set forth below, Plaintiff has not pled sufficient facts to plausibly show that it was unsafe. Nor has she pled any facts to support the assertion that it was ineffective. Further, Plaintiff claims that she "paid for the Defendant's pelvic mesh product" without describing how much she paid. *Id.*, ¶171. Accordingly, her unjust enrichment claim should be dismissed.

X. Plaintiffs' remaining counts of "Discovery Rule, Tolling and Fraudulent Concealment" (Count X) and Punitive Damages (Count XVI) are not recognized causes of action.

The Court should dismiss Count X ("Discovery Rule, Tolling and Fraudulent Concealment") and Count XVI ("Punitive Damages") because these are not recognized causes of action. As noted in *Pharmacy Servs., Inc. v. Swarovski N. Am. Ltd.*, No. 04-72T, 2006 WL 753055, at *6 (D.R.I. Mar. 21, 2006), punitive damages is a remedy; not a cause of action: "Rhode Island does not recognize a separate cause of action for punitive damages, *per se*. Punitive damages are recoverable only where the plaintiff has proven the elements of a recognized cause of action." Similarly, Count X consists of theories to potentially toll the statute of limitations. Therefore, these remaining counts should be dismissed.

XI. Plaintiff's Complaint is an impermissible "shotgun pleading."

Defendants do not object to a dismissal without prejudice of Plaintiff's Complaint and the Court affording Plaintiff leave to amend her Complaint to attempt to cure certain of the aforementioned deficiencies. In addition to addressing the deficiencies set forth above, the Court should also require Plaintiff to tailor her Amended Complaint to Plaintiff, the specific device implanted in her—TVT—and to her specific claims against each of the Defendants.

The First Circuit has recognized that a complaint is an impermissible "'shotgun' pleading" if it "fails to identify claims with sufficient clarity to enable a defendant to frame a responsive pleading." *U.S. ex rel. Estate of Cunningham v. Millennium Labs. of Calif., Inc.*, 713 F.3d 662, 664 (1st Cir. 2013). As noted by the Eleventh Circuit, there are four basic types of "shotgun pleadings": "(1) those in which "each count adopts the allegations of all preceding counts;" (2) those that do not re-allege all preceding counts but are "replete with conclusory, vague, and immaterial facts not obviously connected to any particular cause of action"; (3) those that do not separate each cause of action or claim for relief into a different count; and (4) those that assert multiple claims against multiple defendants without specifying which applies to which." *Yeyille v. Miami Dade Cty. Pub. Sch.*, 643 F. App'x 882, 884 (11th Cir. 2016) (quoting *Weiland v. Palm Beach Cty. Sheriff's Office*, 792 F.3d 1313, 1321-23 (11th Cir. 2015)). "The unifying characteristic of all types of shotgun pleadings is that they fail to one degree or another, and in one way or another, to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests." *Weiland*, 792 F.3d at 1323.

Here, Plaintiff's Complaint is a classic shotgun complaint in many respects. Each Count generically "incorporates by reference each and every paragraph of this Complaint as if fully set forth herein," (*see, e.g.*, Compl., ¶¶58, 66, 71, 76, 83), and it does not distinguish between alleged conduct of Ethicon, Inc. and alleged conduct of Johnson & Johnson.

More problematically, the Complaint is replete with generic allegations about Defendants' mesh products that are not tied to this Plaintiff or the device that was actually implanted in this case—TVT. Confusingly, rather than tailoring her allegations to TVT, Plaintiff vaguely alleges that "Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the **products**" and that "Defendants' negligence caused the **products** to be unreasonably dangerous and defective." Compl., ¶¶60-61 (emphasis added).

Plaintiff, however, does not allege that she was implanted with more than one product. Instead, she merely alleges that she was implanted with a TVT on one occasion in 2011. *Id.*, ¶2. And even though TVT is only used to treat SUI, Plaintiff's Complaint is replete with allegations about other mesh products that are used to treat pelvic organ prolapse—a condition that Plaintiff does not even allege that she had. For instance, Plaintiff alleges that Defendants failed to warn about risks associated for the "treatment of pelvic organ prolapse" but cannot explain how that has anything to do with this case. *Id.*, ¶57o-q. Indeed, none of her Counts even references TVT.

Recently, a Florida federal district court dismissed a similar complaint that broadly referenced Defendants' "pelvic mesh products" without tailoring the allegations to the specific device implanted in the plaintiff, reasoning as follows:

> The First Amended Complaint continues to contain conclusory, vague, and immaterial facts. For example, it broadly collectively defines the medical device implanted in Gergenti with at least five other discrete products and makes vague references to other pelvic mesh products potentially intended to be included in the definition of "Pelvic Mesh Products." It goes without saying that medical devices not implanted are irrelevant to her claims. Yet that is what the First Amended Complaint does. Gergenti bases her claims on a "Pelvic Mesh Product," apparently not distinguishing the relevant Gynecare TVT Secur from other products allegedly manufactured, designed, marketed, or sold by Defendants. The use of this collective definition in describing the relevant product upon which Gergenti's claim rests creates unnecessary ambiguity. Gergenti's failure to adequately describe the medical device at issue in this products liability case

> makes it difficult, if not impossible, for Defendants to properly respond. The Court thus dismisses the First Amended Complaint as an impermissible shotgun pleading.

Gergenti v. Ethicon, Inc., 2020 WL 7695646, at *2 (M.D. Fla. Dec. 28, 2020) (citations omitted); *see also Gergenti v. Ethicon, Inc.*, 2020 WL 5642001, at *2 (M.D. Fla. Sept. 22, 2020) (dismissing the plaintiff's initial complaint as a "textbook shotgun pleading" because "[e]ach count adopts the allegations of each proceeding count" and it "also mixes several claims against the two Defendants without specifying which Defendant is responsible for which acts or omissions").

Indeed, given that Plaintiff's Complaint virtually mirrors numerous other Complaints filed across the country, it is clear that her counsel has endeavored to craft a generic "one size fits all" pleading rather than setting forth factual allegations that are tailored to each individual case. Such a classic shotgun pleading is improper and, accordingly, the Court should require any Amended Complaint to cure these deficiencies set forth in the original Complaint.

CONCLUSION

For the foregoing reasons, Defendants request that the Court dismiss Plaintiffs' Complaint.

ETHICON, INC. and JOHNSON & JOHNSON,

By their Attorneys,

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CERTIFICATE OF SERVICE

I, Kathleen M. Guilfoyle, hereby certify on this 12th day of March, 2021, I have filed the above and foregoing pleading electronically with the Clerk of Court using the CM/ECF system, which will serve notice of all counsel of record.

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